

PATENT COOPERATION TREATY

From the
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
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01 JUL 2008

Applicant's or agent's file reference

32329

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/IL06/00834

International filing date (day/month/year)

19 July 2006 (19.07.2006)

Priority date (day/month/year)

19 July 2005 (19.07.2005)

International Patent Classification (IPC) or both national classification and IPC

IPC: A61B 6/00(2006.01)

USPC: 600/436

Applicant

SPECTRUM DYNAMICS LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US,
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Date of completion of this opinion

11 June 2008 (11.06.2008)

Authorized officer

Ruth Smith

Telephone No. 571-272-4745

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL06/00834

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43b/s.1(a)).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:
- a. type of material
- ☐ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ on paper
- ☐ in electronic form
- c. time of filing/furnishing
- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Form PCT/ISA/237(Box No. I) (April 2007)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITYInternational application No.
PCT/IL06/00834**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)

Claims Please See Continuation Sheet YESClaims Please See Continuation Sheet NO

Inventive step (IS)

Claims Please See Continuation Sheet YESClaims Please See Continuation Sheet NO

Industrial applicability (IA)

Claims Please See Continuation Sheet YESClaims Please See Continuation Sheet NO**2. Citations and explanations:**

Please See Continuation Sheet

Form PCT/ISA/237 (Box No. V) (April 2007)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITYInternational application No.
PCT/IL06/00834

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448

The opinion as to Novelty was negative (No) with respect to claims NONE

The opinion as to Inventive Step was positive (Yes) with respect to claims NONE

The opinion as to Inventive Step was negative (NO) with respect to claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

V. 2. Citations and Explanations:

Claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448 lack an inventive step under PCT Article 33(3) as being obvious over DeVito et al.

DeVito et al. show a SPECT type of tomographic imaging system. The system can move in relation to the patient (column 6, lines 29-40). The system can accept user inputted commands or data to control the system (column 13, lines 35-67). The system is described for use in a heart perfusion study. The patient is given either a physical or pharmacologic stress. During stress, a radiopharmaceutical is then administered, and the patient is imaged. After a period of rest, another dose is administered and the patient is imaged again. The images of the stress period and rest period are compared. Such a technique is common and well known in the art for a myocardial perfusion study (column 24, lines 9-50). DeVito et al. further discusses imaging the brain, breast, or limbs.

It would be obvious to one of ordinary skill in the art, at the time the invention was made, to have imaged other parts of the body. Techniques for imaging other parts of the body are well known in the art, and would be administered to a patient suffering a condition in any other part of the body which would require imaging to evaluate. In addition, the use of a variety of different radiopharmaceuticals could be used in such a system, so long as they allow for the patient to be imaged appropriately. Also, the specific length of times for which the patient should be rested, stressed, and imaged can be different for different patients, and a physician would be able to determine the appropriate length of time. The physician will also be able to determine the appropriate dosage to administer to the patient.

Claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448 lack an inventive step under PCT Article 33(3) as being obvious over Ryals et al.

Ryals et al. show a method and apparatus for SPECT imaging. Ryals et al. describe SPECT systems which are moved around the area to be imaged, and notes that such systems are well known in the art. Ryals et al. also describe common cardiac perfusion studies, which involve examining the heart under a stress condition and a rest condition. The radionuclide introduced to the heart will follow the blood flow, and perfusion can be determined. Infarct and ischemic areas of the heart can be identified (column 1, line 40-column 2, line 24; also column 8, line 56-column 9, line 15; column 16, line 61-column 17, line 20).

It would be obvious to one of ordinary skill in the art, at the time the invention was made, to have imaged other parts of the body. Techniques for imaging other parts of the body are well known in the art, and would be administered to a patient suffering a condition in

Form PCT/ISA/237 (Supplemental Box) (April 2007)

**WRITTEN OPINION OF THE
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PCT/IL06/00834**Supplemental Box**
In case the space in any of the preceding boxes is not sufficient.

any other part of the body which would require imaging to evaluate. In addition, the use of a variety of different radiopharmaceuticals could be used in such a system, so long as they allow for the patient to be imaged appropriately. Also, the specific length of times for which the patient should be rested, stressed, and imaged can be different for different patients, and a physician would be able to determine the appropriate length of time. The physician will also be able to determine the appropriate dosage to administer to the patient.

Claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448 lack an inventive step under PCT Article 33(3) as being obvious over Bishop et al.

Bishop et al. show a cardiovascular imaging and functional analysis system. The use of such a system for myocardial perfusion studies under stress is discussed ([0077]). The use of different types of radiopharmaceuticals is discussed ([0118]-[0120], [0125]).

It would be obvious to one of ordinary skill in the art, at the time the invention was made, to have imaged other parts of the body. Techniques for imaging other parts of the body are well known in the art, and would be administered to a patient suffering a condition in any other part of the body which would require imaging to evaluate. In addition, the use of a variety of different radiopharmaceuticals could be used in such a system, so long as they allow for the patient to be imaged appropriately. Also, the specific length of times for which the patient should be rested, stressed, and imaged can be different for different patients, and a physician would be able to determine the appropriate length of time. The physician will also be able to determine the appropriate dosage to administer to the patient.

Claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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